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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/607,524

06/26/2003

Tenny Chang

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09/19/2006

CARDICA, INC.

900 SAGINAW DRIVE

REDWOOD CITY, CA 94063

EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/607,524

Applicant(s)

CHANG ET AL.

Examiner

Diane Yabut

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 and 41-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 and 41-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/26/03;2/6/04;6/17/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS: 4/29/05;1/27/06</u> . |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group 1, Claims 1-30 and 41-53 in the reply filed on 18 July 2006 is acknowledged.
2. Claims 31-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 18 July 2006.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 26 June 2003 is acknowledged. In addition, the information disclosure statements submitted on 6 February 2004, 17 June 2004, 29 April 2005, and 27 January 2006 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Specification

4. The abstract of the disclosure is objected to because on line 6 of the abstract it reads "holder" when it should instead read --hold--. Correction is required. See MPEP § 608.01(b).
5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is

Art Unit: 3734

requested in correcting any errors of which applicant may become aware in the specification.

Drawings

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "upper edge **715**" is not found in any of the figures. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

7. Claims 1, 28, 42, 46, 50, and 51 are objected to because of the following informalities:

On both line 5 of Claim 1 and line 2 of Claim 42 it reads "a edge" and should be changed to --an edge--. On line 1 of Claims 28 and Claim 46 it reads "moveable" and should be changed to --movable--. On line 3 of Claim 50 it reads "at least one flap" and

Art Unit: 3734

should be changed to --at least one said flap-- or --the at least one flap--. On line 2 of Claim 51 it reads "least one flap receiving surface" and should instead read --least one said flap receiving surface--. Appropriate correction is required.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-5, 8-11, 13-15, and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Stefanchik et al., or **Stefanchik '019**, (U.S. Patent No. **6,187,019**) in view of Stefanchik et al., or **Stefanchik '700**, (U.S. Patent No. **6,036,700**).

Claims 1 and 10: Stefanchik '019 discloses a transfer clamp **80** including two arms **84** and **82**, wherein at least one said arm comprises at least one element having an edge **L**, wherein the length of said edge is related to the anastomosis length (Figure 5).

Stefanchik '019 discloses the claimed device except for the two arms being movable relative to one another, between an open position and a closed position.

Stefanchik '700 teaches two arms **118** and **128** being movable relative to one another, between an open position and closed position (Figures 10-11). It would have been obvious to one of ordinary skill in the art at the time of invention to provide mutually relatively movable arms, movable between open and closed positions, as

Art Unit: 3734

taught by Stefanchik '700, to Stefanchik '019 since it was known in the art that relatively movable arms achieve more flexibility for grasping and maneuvering around tissue.

Claims 2-4: Stefanchik '019 discloses jaws, the jaws being the inner surfaces of **84** and **82**, connected to said arm, fixed to said arm, and movable relative to the opposing arm (Figure 5, col. 6, lines 4-6).

Claims 8-9: Stefanchik '019 discloses the one element being a portion of said arm and having a gripping surface defined thereon, wherein "gripping surface" is taken to mean a surface that can grip onto tissue (Figure 5).

Claim 11: Stefanchik '019 discloses the claimed device except for arms being biased to said closed position.

Stefanchik '700 teaches two arms **18** and **28** being biased to a closed position (col. 6, lines 30-34). It would have been obvious to one of ordinary skill in the art to provide arms being biased to a closed position, as taught by Stefanchik '700, to Stefanchik '019 since it was known in the art that clamping or grasping members that are biased or remain in a closed position, or grasping position, do not require an additional device or mechanism to hold the grasping member in a closed position.

Claim 13: Stefanchik '019 discloses a transfer clamp being configured to engage an anastomosis tool (Figure 5).

Claim 14: Stefanchik '019 discloses a transfer clamp including a stop **85** or **83** configured to contact an anastomosis tool (Figure 5).

Art Unit: 3734

Claim 15: Stefanchik '019 discloses a transfer clamp being configured to lock onto the anastomosis tool, wherein "lock" taken to mean "temporarily stop the motion of a mechanism" (Figure 5).

Claims 18-22: Stefanchik '019 discloses an extension arm **110** including a poke-through tip that is soft, substantially rigid, substantially tubular, and located at one end of the extension arm (Figure 12 and col. 7, lines 52-64).

10. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stefanchik '019** (U.S. Patent No. **6,187,019**) and **Stefanchik '700**, (U.S. Patent No. **6,036,700**), as applied to Claim 1 above, and further in view of Vargas et al., or **Vargas '166** (U.S. Pub. No. **20020095166**).

Claims 5-7: Stefanchik '019 and Stefanchik '700 disclose the claimed device except for a cutting block movable and rotatable relative to the corresponding arms.

Vargas '166 teaches a cutting block **206a'-2** movable and rotatable relative to the corresponding arm **206a'** that prevents further cutting of the incision (Figure 10A and page 4, paragraph 56). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a rotatable cutting block relative to the corresponding arm, as taught by Vargas '166 to Stefanchik '019 and Stefanchik '700 in order to prevent further cutting of the incision.

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Stefanchik '019** (U.S. Patent No. **6,187,019**) and **Stefanchik '700**, (U.S. Patent No.

Art Unit: 3734

6,036,700), as applied to Claim 11 above, and further in view of **Tartaglia** (U.S. Patent No. **4,318,313**).

Claim 12: Stefanchik '019 and Stefanchik '700 disclose the claimed device, including compression of the arms moving the arms from said closed position to an open position (Stefanchik '700, Figures 10-11), except for finger pads being coupled to said arms, wherein compression of said finger pads move said arms from said closed position to said open position. It is noted that the finger pads themselves are not the cause of moving the arms from a closed position to an open position, but rather they are coupled to the arms that are compressed, moving the arms from a closed position to an open position.

Tartaglia teaches finger pads **20** and **20'** being coupled to arms **10** and **10'** which provides the user a larger surface area onto which they may place their fingers to prevent slippage, as well as ergonomic benefits (Figure 1 and col. 2, lines 4-8). It would have been obvious to one of ordinary skill in the art to provide finger pads coupled to the arms, as taught by Tartaglia, to Stefanchik '019 and Stefanchik '700, in order to provide the user with ergonomic benefits in using the device.

11. Claims 23-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stefanchik '019** (U.S. Patent No. **6,187,019**) and **Stefanchik '700**, (U.S. Patent No. **6,036,700**), as applied to Claim 18 above, and further in view of **Person** (U.S. Patent No. **6,200,263**).

Art Unit: 3734

Claims 23-27: Stefanchik '019 and Stefanchik '700 disclose the claimed device except for a retractor mount connectable to an extension arm, a holder being movable and rotatable relative to a remainder of the retractor mount, being connectable to said extension arm via said holder, and being configured to engage said anastomosis tool.

Person teaches a retractor mount **10** adapted to be connectable to an extension arm, a holder **30** being movable and rotatable relative to a remainder of the retractor mount, being adapted to be connectable to an extension arm via said holder, and being configured to engage an anastomosis tool (Figure 3 and col. 2, lines 29-46). Person teaches that a retractor mount with a holder provides greater versatility, is less invasive, and facilitates selective position adjustment of instruments relative to the retractor mount (col. 2, lines 2-5 and 14-18). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a rotatable holder connected to a retractor mount, as taught by Person, to Stefanchik '019 and Stefanchik '700, in order to provide greater versatility, to be less invasive, and to facilitate selective position adjustment of instruments.

12. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stefanchik '019** (U.S. Patent No. **6,187,019**) and **Stefanchik '700**, (U.S. Patent No. **6,036,700**), as applied to Claim 1 above, and further in view of **Carranza et al.** (U.S. Patent No. **6,821,286**).

Claims 28-30: Stefanchik '019 and Stefanchik '700 disclose the claimed device except for a graft manipulator being movable relative to the transfer clamp, including

Art Unit: 3734

two members spaced apart from and biased from one another, and a prong connected to the distal end of at least one said member.

Carranza et al. teaches a graft manipulator, such as forceps or tweezers, configured to be movable relative to a transfer clamp, including two members spaced apart from and biased from one another, and a prong connected to the distal end of at least one said member, wherein "prong" is taken to mean "projecting part," (col. 1, lines 27-40). It would have been obvious to one of ordinary skill in the art to provide a graft manipulator, as taught by Carranza et al., to Stefanchik '019 and Stefanchik '700, since it was known in the art that a graft vessel must be manipulated by a mechanism that expands or spreads the end of a graft vessel so that it may be received by an anastomosis device without injuring the graft vessel.

13. Claims 41-42, 45, and 47-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stefanchik '019** (U.S. Patent No. **6,187,019**) in view of Vargas et al., or **Vargas '353** (U.S. Pub. No. **20010023353**).

Claims 41 and 49-51: Stefanchik '019 discloses a transfer clamp, or a mechanism configured to register a graft vessel relative to a tissue effector, and adapted to be connectable to a tissue effector, the mechanism being configured to register at least one flap with at least one flap receiving surface (see paragraph 9 above). Stefanchik '019 discloses the claimed device except for a tissue effector comprising an anvil and a staple holder movable relative to said anvil, as well as at least one flap located at an end of the graft vessel, wherein said staple holder includes at least one flap receiving

Art Unit: 3734

surface, and wherein said mechanism is configured to register at least one said flap with at least one said flap receiving surface, and at least one spike extending from the at least one flap receiving surface.

Vargas '353 teaches a tissue effector comprising an anvil **10** and a staple holder **38** movable relative to said anvil, at least one flap located at an end of the graft vessel **32**, wherein said staple holder **38** includes at least one flap receiving surface **40** which has at least one spike extending from the at least one flap receiving surface, and also teaches that the anastomosis system is useful in supporting a wall of a coronary artery during attachment and controls very thin tissues (Figures 1 and 5, page 2, paragraph 45 and page 3, paragraph 50). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a tissue effector comprising an anvil and a staple holder movable to said anvil, which has at least one flap receiving surface with a spike, as taught by Vargas '353, to Stefanchik '019 in order to support the thin wall of the coronary artery during attachment.

Claim 42: Stefanchik '019 discloses a transfer clamp including at least one said arm, wherein at least one said arm comprises at least one element having an edge, wherein the length of the edge is related to anastomosis length (see paragraph 9 above).

Claim 45: Stefanchik '019 discloses a poke-through tip connected to said transfer clamp (see paragraph 9 above).

Claim 47: Stefanchik '019 discloses a transfer clamp being configured to register the graft vessel relative to said tissue effector (see paragraph 9 above).

Art Unit: 3734

Claim 48: Stefanchik '019 discloses a transfer clamp being configured to positively engage said tissue effector (see paragraph 9 above).

Claim 52: Stefanchik '019 discloses said mechanism being connectable to said tissue effector (see paragraph 9 above).

Claim 53: Stefanchik '019 discloses said mechanism being configured to positively engage said tissue effector (see paragraph 9 above).

14. Claims 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stefanchik '019** (U.S. Patent No. **6,187,019**) and **Vargas '353** (U.S. Pub. No. **20010023353**), as applied to Claim 42 above, and further in view of **Vargas '166** (U.S. Pub. No. **20020095166**).

Claims 43 and 44: Stefanchik '019 and Vargas '353 disclose the claimed device except for the one element being a cutting block, rotatable relative to the corresponding said arm.

Vargas '166 teaches one element being a cutting block, rotatable relative to a corresponding arm (see paragraph 10 above).

14. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Stefanchik '019** (U.S. Patent No. **6,187,019**) and **Vargas '353** (U.S. Pub. No. **20010023353**), as applied to Claim 41 above, and further in view of **Carranza et al.** (U.S. Patent No. **6,821,286**).

Art Unit: 3734

Claim 46: Stefanchik '019 and Vargas '353 disclose the claimed device except for a graft manipulator relative to said transfer clamp.

Carranza et al. teaches a graft manipulator movable relative to a transfer clamp (see paragraph 12 above).

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **Borst et al** (U.S. Patent No. **6,394,948**) discloses a retractor mount with an instrument holder, **Swayze et al.** (U.S. Patent No. **6,530,932**) discloses a poke-through tip.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

A handwritten signature in black ink, appearing to read "MJ Hayes", with a long horizontal stroke extending to the right.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER